

### **AMENDMENTS TO THE CLAIMS**

This listing of claims will replace all prior versions, and listings, of claims in the application.

#### **Listing of Claims:**

1. **(Withdrawn)** A process for producing recombinant cytokine, comprising:  
  
producing a recombinant silkworm comprising a cytokine gene in a chromosome of the recombinant silkworm,  
  
producing recombinant cytokine protein in a silk gland, a cocoon or a silk thread of the recombinant silkworm, and  
  
recovering the recombinant cytokine protein from the silk gland, cocoon or silk thread of the recombinant silk worm.
  
2. **(Withdrawn)** The process for producing recombinant cytokine according to claim 1, wherein the cytokine gene encoding the recombinant cytokine protein is coupled downstream from a promoter specifically expressed in *Bombyx mori* silk glands, and wherein the cytokine gene and the promoter are incorporated in a chromosome.
  
3. **(Withdrawn)** The process for producing recombinant cytokine according to claim 2, wherein the promoter specifically expressed in *Bombyx mori* silk glands is a sericin gene promoter.

4. **(Withdrawn)** The process for producing recombinant cytokine according to claim 2, wherein the promoter specifically expressed in *Bombyx mori* silk glands is a fibroin H chain gene promoter.

5. **(Withdrawn)** The process for producing recombinant cytokine according to any one of claims 1 through 4, wherein the cytokine gene is incorporated in *Bombyx mori* silkworm chromosomes using DNA originating in a transposon.

6. **(Withdrawn)** The process for producing recombinant cytokine according to claim 5, wherein the cytokine gene is located between a pair of inverted terminal sequences originating in a transposon.

7. **(Withdrawn)** The process for producing recombinant cytokine according to claim 5, wherein the DNA originating in a transposon originates in an insect.

8. **(Withdrawn)** The process for producing recombinant cytokine according to claim 7, wherein the transposon originates in a piggyBac transposon originating in a lepidopteron.

9. **(Withdrawn)** The process for producing recombinant cytokine according to claim 1 wherein the cytokine gene is a gene encoding interferon or a gene encoding colony stimulating factor.

10. **(Withdrawn)** The process for producing recombinant cytokine according to claim 9, wherein the interferon gene or the colony stimulating factor gene is feline interferon- $\omega$  gene, human interferon- $\beta$  gene or feline granulocyte colony stimulating factor gene.

11. **(Withdrawn)** The process for producing recombinant cytokine according to any one of claims 1 through 3, wherein cytokine is extracted from cocoon and silk thread by contacting the cocoon and silk thread with an aqueous solvent.

12. **(Withdrawn)** A recombinant *Bombyx mori* silkworm in which a cytokine gene has been inserted into a chromosome and cytokine is produced in the silkworm silk glands, cocoon or silk thread.

13. **(Withdrawn)** The recombinant silkworm according to claim 12, wherein the cytokine gene inserted into a chromosome is an interferon gene or colony stimulating factor gene.

14. **(Withdrawn)** The recombinant silkworm according to claim 13, wherein the interferon gene or colony stimulating factor gene inserted into a chromosome is feline interferon- $\omega$  gene, human interferon- $\beta$  gene or feline granulocyte colony stimulating factor gene.

15. **(Withdrawn)** A vector for inserting an exogenous gene into *Bombyx mori* silkworm chromosomes, wherein said vector comprises a cytokine gene coupled downstream from a promoter that is specifically expressed in *Bombyx mori* silk glands.

16. **(Withdrawn)** The vector for inserting an exogenous gene into *Bombyx mori* silkworm chromosomes according to claim 15, wherein the promoter is sericin gene promoter.

17. **(Withdrawn)** The vector for inserting an exogenous gene into *Bombyx mori* silkworm chromosomes according to claim 15, wherein the promoter is a fibroin H chain gene promoter.

18. **(Withdrawn)** The vector for inserting an exogenous gene into *Bombyx mori* silkworm chromosomes according to any one of claims 15 through 17, wherein the cytokine gene is located between a pair of inverted terminal sequences originating in a transposon.

19. **(Withdrawn)** The vector for inserting an exogenous gene into *Bombyx mori* silkworm chromosomes according to claim 15, wherein the cytokine gene is an interferon gene or a colony stimulating factor gene.

20. **(Withdrawn)** The vector for inserting an exogenous gene into *Bombyx mori* silkworm chromosomes according to claim 19, wherein the interferon gene or colony stimulating factor gene is feline interferon- $\omega$  gene, human interferon- $\beta$  gene or feline granulocyte colony stimulating factor gene.

21. **(Currently Amended)** A gene cassette for expressing an exogenous protein comprising in order:

- (1) an inverted repetitive sequence of a piggyBac transposon;
- (2) an approximately 5500 base pair sequence comprising nucleotides 57444 to 62927 of GenBank Accession No. AF 226688 1-5484 of SEQ ID NO:23;
- ~~(3) a fibroin H chain gene promoter expressed in *Bombyx mori* silk glands;~~
- [[ (4) ] [a] (3) an exogenous protein gene coupled downstream from (2) ~~the promoter,~~  
~~wherein the 5' terminal portion of a fibroin H chain gene of *Bombyx mori* is fused to the 5' side of an exogenous protein structural gene ; and~~
- [[ (5) ] (4) an inverted repetitive sequence of a piggyBac transposon.

22. **(Cancelled).**

23. **(Currently Amended)** A gene cassette for expressing an exogenous protein comprising in order:

- (1) an inverted repetitive sequence of a piggyBac transposon;
- (2) an approximately 5500 base pair sequence comprising nucleotides ~~57444 to 62927 of~~  
~~GenBank Accession No. AF-226688~~ 1-5484 of SEQ ID NO:23;
- ~~(3) a fibroin H chain gene promoter expressed in *Bombyx mori* silk glands;~~
- [[~~(4)~~]] [[a]] (3) an exogenous protein gene not containing a stop codon coupled  
downstream from (2);
- ~~the promoter, wherein a 5' terminal portion of a fibroin H chain gene of *Bombyx mori* is~~  
~~fused to the 5' side of an exogenous protein structural gene not containing a stop codon, and~~
- (4) a 3' terminal portion of the fibroin H chain gene [[is]] fused to the 3' side of an  
exogenous protein structural gene; and
- (5) an inverted repetitive sequence of a piggyBac transposon.

24. **(Previously Presented)** The gene cassette according to claim 21 or claim 23, wherein the 5' terminal portion of the fibroin H chain gene contains a first exon, first intron and a portion of a second exon of the fibroin H chain gene.

25. **(Cancelled)**

26. **(Previously Presented)** The gene cassette according to claim 24, wherein the upstream region, the promoter and the 5' terminal portion together comprise the DNA as shown in SEQ ID NO: 23.

27. **(Currently Amended)** The gene cassette according to claim ~~[[22 or]]~~ 23, wherein the 3' terminal portion of the fibroin H chain gene contains at least one codon that encodes cysteine.

28. **(Previously Presented)** The gene cassette according to claim 27, wherein the 3' terminal portion of the fibroin H chain gene consists of the DNA shown in SEQ ID NO: 24.

29. **(Cancelled)**

30. **(Currently Amended)** The gene cassette according to ~~any one of claims 21 through~~ or 23, wherein a poly A addition region of fibroin H chain gene is present downstream from the gene cassette.

31. **(Currently Amended)** A gene cassette for inserting a gene into chromosomes of insect cells comprising inverted repetitive sequences of a pair of piggyBac transposons present on both sides of the gene cassette according to ~~any one of claims 21 through~~ or 23.

32. **(Currently Amended)** An expression vector for insect cells that contains the gene cassette according to ~~any one of claims 21 through~~ or 23.

33. **(Previously Presented)** A gene insertion vector for insect cells that contains the gene cassette of claim 31 for inserting a gene into chromosomes of insect cells.

34. **(Previously Presented)** A process for producing an exogenous protein comprising inserting the vector for insect cells according to claim 32 into insect cells.

35. **(Previously Presented)** The process for producing an exogenous protein according to claim 34, wherein the insect cells originate in a lepidopteron.

36. **(Previously Presented)** The process for producing the exogenous protein according to claim 35, wherein the insect cells originate in *Bombyx mori*.

37. **(Previously Presented)** The process for producing an exogenous protein according to claim 36, wherein the insect cells are silk gland cells of *Bombyx mori*.

38. **(Currently Amended)** A process for producing an exogenous protein comprising producing a recombinant silkworm in which the gene cassette according to ~~any one of~~ claims 21 ~~through or~~ 23 is inserted into a chromosome using a gene insertion vector for insect cells and the DNA transfer activity of piggyBac transposase, producing exogenous protein in the silk glands or cocoon and silk thread of the resulting recombinant silkworm, recovering the exogenous protein from the silk glands or silk and cocoon thread in an aqueous solution.



39. **(Previously Presented)** The process for producing an exogenous protein according to claim 38, wherein the recombinant silkworm, in which the gene cassette for expressing an exogenous protein has been inserted into a chromosome, is produced by simultaneously micro-injecting the gene insertion vector for insect cells and DNA or RNA that produces the piggyBac transposase into silkworm eggs.

40. **(Withdrawn)** A recombinant silkworm in which a gene cassette for expressing an exogenous protein according to any of claims 21 through 31 has been inserted into a chromosome, and which has the ability to produce the exogenous protein in silk glands or silk thread.

41. **(Withdrawn)** Silk thread containing an exogenous protein produced by a recombinant silkworm according to claim 40.

42. **(Previously Presented)** A process for producing an exogenous protein comprising inserting the vector for insect cells according to claim 33 into insect cells.

43. **(Previously Presented)** The process for producing an exogenous protein according to claim 42, wherein the insect cells originate in a lepidopteron.

44. **(Previously Presented)** The process for producing the exogenous protein according to claim 43, wherein the insect cells originate in *Bombyx mori*.

45. **(Previously Presented)** The process for producing an exogenous protein according to claim 44, wherein the insect cells are silk gland cells of *Bombyx mori*.